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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of)

Group Art Unit 3775

Jean-François BIEGUN and)
Pascal MARCEAUX)

Nicholas W. Woodall, Examiner

Serial No.: 10/534,567)

Filed: May 12, 2005)

For: ACCESSORIES FOR)
REMOVING BONE MATERIAL)
AND METHOD FOR MAKING)
SAME)

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Patricia Oakes, Secretary to Edward G. Greive

REPLY BRIEF PURSUANT TO 37 CFR 41.41

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Reply Brief following the Examiner's Answer, which bears a mailing date of January 19, 2011.

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Status of Claims

Claims 1-11, 14, and 22-24 have been cancelled.

Claims 12, 13, 15-21, and 25 have been rejected, and all are appealed.

Grounds of Rejection to Be Reviewed on Appeal

I. Whether claims 12, 13 and 20 fail to comply with the written description requirement of 35 U.S.C. § 112, first paragraph.

II. Whether claim 21 is anticipated by Geisser (U.S. Patent No. 5,454,815)

III. Whether claim 25 is obvious in view of Geisser and Morgan (U.S. Patent No. 5,910,106)

IV. Whether claim 20 is obvious in view of Geisser and Morgan.

The Examiner's Answer does not identify any "WITHDRAWN REJECTIONS" or "NEW GROUNDS OF REJECTION", so the grounds of rejection to be reviewed on appeal remain the same as those identified in the Appeal Brief.

Argument

I. Claims 12, 13 and 20 Are Supported by the Originally Filed Disclosure

The Examiner's Answer maintains the rejection of claims 12, 13 and 20 under 35 U.S.C. § 112, first paragraph, even though the originally filed specification teaches:

1. Tools used to remove bone must be hard enough to do so:
 - a. "This invention relates to instruments or ancillaries used to remove bones for hip or knee prosthetic surgery" (page 1, lines 3-4).
 - b. "Rasps, cutting units and other ancillaries for removing bones are well-known in the field. These ancillaries must be hard enough and sufficiently resistant to wear to be able to attack bone and withstand the heavy pressures resulting from the action of a blade with which they cooperate on bone" (page 1, lines 9-12).
2. The invention includes a rasp made of plastic:
 - a. "By making these ancillaries largely in plastic..." (page 2, line 4)
 - b. "By producing the rasp or cutting unit in this material therefore ..." (page 2, line 17).
3. The plastic is exposed to β or γ rays:
 - a. "The initial sterilization is actually carried out by exposure to γ or β rays" (page 2, line 29).
4. The plastic rasp is hard enough to rasp bone:
 - a. "However, as the plastic used is hard enough, it will be suitable for removing bone and withstanding the pressures associated with the action of a blade on the bone" (page 2, lines 9-11).
 - b. "It transpires, however, that this rasp or cutting unit, which is made at least in part of a thermoplastic material, is perfectly well suited for use" (page 3, lines 14-16).

The test for sufficiency of support in an application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." See,

MPEP 2163.02, citing *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985). The originally filed specification clearly teaches both that (1) the plastic material of a rasp is exposed to β or γ rays, and (2) that the rasp is hard enough to remove bone. Even if features in the claims were not set forth "*in haec verba*" in the specification, there is adequate written description to support them. See, *In re Wright*, 866 F.2d 422, 425, 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989).

The claims being fully supported by the originally filed disclosure, the Examiner's rejections under 35 U.S.C. § 112, first paragraph, should be reversed.

II. The Combination of Geisser and Morgan Does Not Teach Or Suggest Exposing The Plastic Material Of A Rasp To β or γ Rays

Claims 20 and 25 recite features relating to exposing the plastic material of a rasp to β or γ rays. The Examiner points to Morgan for this feature, but this is in error.

Morgan relates to "An instrument heater for heating a surgical instrument." See, Abstract. The surgical instrument is used in surgery, but the instrument heater is not ("Once [the desired] temperature is reached, the instrument heater 21 is removed from the probe 3 and discarded. The probe and the lens 5 are then inserted into the body for examination of the interior of the body."). See, column 5, lines 62-65. Morgan teaches that the instrument heater may be sterilized by exposing it to gamma rays (column 5, lines 40-43), which makes sense since the instrument heater is made of "a thin cardboard type material" (column 4, lines 45-49) and could not be sterilized using conventional heat sterilization. However, Morgan does not teach or suggest that the item actually used in surgery (the probe) is exposed to β or γ rays. In the present application, the rasp is actually used in surgery, and it is exposed to β or γ rays before such use. One of skill in the art would not consider the teachings in Morgan and be motivated to expose a plastic material that is part of a tool used in surgery to β or γ rays.

The Federal Circuit has stated that “rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” See, MPEP § 2142, citing *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). There is no rational underpinning to the combination of Geisser and Morgan, and the rejection should be reversed.

III. Inventor Biegun’s Declarations, Taken in Their Entirety, Overcome the Rejections.

One of the inventors, Jean François Biegun, has been working in the field of prosthesis and ancillaries and accessories for removing hip or knee bone for almost twenty years. See, Declarations of Jean François Biegun filed March 16, 2009 and December 29, 2010. Mr. Biegun’s declarations also establish, *generally*, that “prior art hip rasp such as described in US 5454815...cannot rasp hip bones.”

The Examiner’s consideration of the declarations fails to address them in their entirety. For example, the Examiner’s Answer states at page 8, “the appellant does not provide data for all the different materials disclosed by Geisser, such as polyamides, and therefore has not shown the Geisser reference as being incapable of removing bone.” Even though Mr. Biegun provided data relative to one formulation (a rasp made of polycarbonate), he still testified more broadly that “prior art hip rasp such as described in US 5454815...cannot rasp hip bones.” This testimony was not limited to any particular plastic formulation and was made in view of the knowledge gained during Mr. Biegun’s long tenure in the art area. Moreover, Geisser specifically discloses polycarbonate as a “preferred material” (column 3, lines 14-15), and if the preferred material cannot rasp bone it can be inferred that less preferred materials also do not rasp bone.

Mr. Biegun’s assertions that prior art plastic rasps cannot rasp hip bones are supported by the fact that a later-filed patent to Grünig (U.S. Patent No. 6,120,508) criticized the plastic rasps taught in Geisser as having problems when

used on hard bone material and with longer application times. See, Appeal Brief at Section II.

IV. Conclusion

The 35 U.S.C. §§ 112, 102 and 103 rejections of the Examiner are not sound and should be reversed. The Appellants respectfully request such a finding from the Board.

Respectfully submitted,



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March 15, 2011